

Consensus on Recording Deep Endometriosis Surgery: the CORDES statement[†]

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STUDY QUESTION: Which essential items should be recorded before, during and after endometriosis surgery and in clinical outcome based surgical trials in patients with deep endometriosis (DE)?

SUMMARY ANSWER: A DE surgical sheet (DESS) was developed for standardized reporting of the surgical treatment of DE and an international expert consensus proposal on relevant items that should be recorded in surgical outcome trials in women with DE.

WHAT IS KNOWN ALREADY: Surgery is an important treatment for symptomatic DE. So far, data have been reported in such a way that comparison of different surgical techniques is impossible. Therefore, we present an international expert proposal for standardized reporting of surgical treatment and surgical outcome trials in women with DE.

STUDY DESIGN, SIZE, DURATION: International expert consensus based on a systematic review of literature.

[†]Presented at ESHRE Precongress Course on Endometriosis and Pain, 1 July 2012 during the 28th Annual ESHRE Meeting, Istanbul, Turkey, 1–4th July; at the 2nd Congress of the European Endometriosis League (EEL), (Session 3 'Pain and Cancer'), Berlin, Germany, 28–30 November, 2013 and at the Deep Infiltrating Endometriosis symposium, organized by the Endometriosis and Adenomyosis Society of Turkey together with the Turkish Society of Gynecological Endoscopy, Istanbul, 18–19 January 2014.

PARTICIPANTS/MATERIALS, SETTING, METHODS: Taking into account recommendations from Consolidated Standards of Reporting Trials (CONSORT), the Innovation Development Exploration Assessment and Long-term Study (IDEAL), the Initiative on Methods, Measurement and Pain Assessment in Clinical trials (IMMPACT) and the World Endometriosis Research Foundation Phenome and Biobanking Harmonisation Project (WERF EPHect), a systematic literature review on surgical treatment of DE was performed and resulted in a proposal for standardized reporting, adapted by contributions from eight members of the multidisciplinary Leuven University Hospitals Endometriosis Care Program, from 18 international experts and from audience feedback during three international meetings.

MAIN RESULTS AND THE ROLE OF CHANCE: We have developed the DESS to record in detail the surgical procedures for DE, and an international consensus on pre-, intra- and post-operative data that should be recorded in surgical outcome trials on DE.

LIMITATIONS, REASONS FOR CAUTION: The recommendations in this paper represent a consensus among international experts based on a systematic review of the literature. For several items and recommendations, high-quality RCTs were not available. Further research is needed to validate and evaluate the recommendations presented here.

WIDER IMPLICATIONS OF THE FINDINGS: This international expert consensus for standardized reporting of surgical treatment in women with DE, based on a systematic literature review and international consensus, can be used as a guideline to record and report surgical management of patients with DE and as a guideline to design, execute, interpret and compare clinical trials in this patient population.

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Introduction

Deep endometriosis (DE) is a multifocal pathology which may infiltrate different pelvic locations and organs (Chapron et al., 2010). Surgery for DE appears effective, but is associated with significant complication rates (Dunselman et al., 2014). Several techniques for the excision of DE have been described, but large, prospective RCTs are lacking. Systematic reviews on the surgical treatment of DE demonstrated that it is impossible to compare the literature owing to unclear definitions, lack of standardization and incompleteness in reporting (De Cicco et al., 2011; Meuleman et al., 2011). Therefore, we believe that an initiative is needed for the standardization of data collection in surgical trials on DE.

Inspired by the World Endometriosis Research Foundation Phenome and Biobanking Harmonisation Project (WERF-EPHect) and the IDEAL-recommendations (Innovation Development Exploration Assessment and Long-term study) for improving surgical innovation and evaluation, we present in this paper a Consensus On Recording Deep Endometriosis Surgery (CORDES) (McCulloch et al., 2009; Casper, 2014). This Executive Summary of the CORDES statement summarizes two full-length articles that are available online in *Human Reproduction*: in the first article (Vanhie et al., 2016 Part I, Supplementary Data) we propose a deep endometriosis surgical sheet (DESS) for the standardized reporting of surgery for DE; in the second article (Vanhie et al., 2016 Part II, Supplementary Data) we present a consensus for the standardization of reporting surgical trials in patients with DE.

Methods

A systematic literature search was performed using the search terms 'deeply infiltrating endometriosis' and 'deep endometriosis' in combination with 'treatment'. A total of 26 reviews, systematic reviews and meta-analyses

were identified and analyzed in detail for data about reporting of endometriosis surgery. Through cross-referencing 25 additional relevant publications were identified and included (Vanhie et al., Part I, Supplementary Table SI).

CORDES Part I: standardized reporting of surgical procedures (Vanhie et al., 2016 Part I)

Based on the results of this literature search, the WERF-EPHect surgical form (Becker et al., 2014) and an existing checklist (Meuleman et al., 2011, 2012), we developed a first draft version of the 'deep endometriosis surgical sheet' (DESS), where all items were precisely defined.

This draft was then reviewed and adapted by senior staff members of the multidisciplinary Leuven Endometriosis Surgical Team until a consensus was reached. During the next stage, international experts were contacted and were asked to offer feedback. All authors reviewed the manuscript and provided feedback, gave comments and/or added items. This resulted in the final version of the DESS, which was then presented for approval to all coauthors (Vanhie et al., 2016 Part I).

CORDES Part II: standardized reporting of surgical trials (Vanhie et al., 2016 Part II)

Based on the results of the literature search, we extended an existing CONSORT-based checklist (Meuleman et al., 2011, 2012) to delineate the essential items in reporting of baseline data, interventions and outcome assessment. Subsequently, all items from the extended checklist were precisely defined and the checklist was adapted until consensus was reached among the members of the multidisciplinary Leuven Endometriosis Surgical Team.

During the second stage, international experts were contacted and asked to offer feedback. All authors reviewed the manuscript, provided feedback, gave comments and/or added items. This resulted in the final version of the international expert consensus, which was approved by all coauthors.

Results

In Part I we have developed the DESS, which is available as an online publication in *Human Reproduction* (Vanhie et al., 2016 Part I). In Table I an overview of the recommendations in the DESS is presented. In the online paper we also propose detailed definitions for all surgical procedures used in the treatment of DE (Vanhie et al., 2016 Part I).

In Part II we have developed an international expert consensus on the reporting of surgical trials in women with DE, which is available as a second online publication in *Human Reproduction* (Vanhie et al., 2016 Part II). In Table II a general overview is presented of these recommendations for standardized reporting of surgical trials in women with DE. In the online paper, we also propose definitions for different types of recurrence of endometriosis and all other items used in the CORDES statement (Vanhie et al., 2016 Part II).

Table I Standardized reporting of surgical treatment for deep endometriosis: summary of the deep endometriosis surgical sheet (DESS).

Record essential pre-operative information

- Essential clinical covariates
 - Menstrual history and current hormonal treatment
 - Previous endometriosis surgery
 - Pre-operative imaging results
 - Use of prophylactic drugs
- Indications and decision on type of surgery

Record detailed description and staging of endometriosis

- Staging: ASRM and EFI (optional: ENZIAN)
- Extent of peritoneal/superficial endometriosis
 - Number, size and exact localization of each lesion
- Extent of ovarian endometriosis
 - Number, size and localization of endometrioma(s)
- Extent of deep endometriosis
 - Number, size and exact localization of each lesion
 - Bowel DE:
 - Depth of infiltration in intestinal wall
 - Circumferential involvement
 - Distance to anal verge
 - Urological DE:
 - Depth of infiltration in bladder and ureter
 - Presence of hydro-ureteronephrosis
- Extent of adhesions

Record detailed description of surgical procedures performed

- Clear description of surgical procedures performed (standardized terminology)
- Record surgical risk factors for negative outcomes

Record essential post-operative information

- Operation times, length of hospital stay and post-operative management
- Detailed description of the abdomen after surgery
- Detailed histological report
- Intra and post-operative complications

ASRM, American Society for Reproductive Medicine; EFI, endometriosis fertility index; DE, deep endometriosis.

Conclusion

The DESS (Vanhie et al., 2016 Part I) is an exhaustive surgical sheet including more items than routinely recorded in current research databases, and including all items of the WERF EPHeCT surgical form, which is a first major strength (Becker et al., 2014). This ensures that the recorded information cannot only be used for surgical research purposes but is also aligned with the EPHeCT standard for biobank samples and endometriosis research in general, which compensates for the extra time invested in the recording of the DESS. A second very important strength of the DESS is its 'ready to use' format which allows easy implementation, also for centers that do not routinely record and report their surgical data. A third strength is that the DESS can be used as a basis for national/inter-national registries, allowing each registration authority flexibility in quality control by defining essential and non-essential fields within the DESS.

In Part II of the CORDES statements (Vanhie et al., 2016 Part II) we included, where possible, patient reported outcomes for the assessment of different aspects relevant in trials on surgical management of endometriosis. Recently, patient reported outcomes related to quality of life have been used increasingly and have been widely accepted as a solid primary outcome measure in scientific trials (Kluivers et al., 2008; Vincent et al., 2010). The majority of other outcome variables recommended in Part II (Vanhie et al., 2016 Part II) have been selected because they are well known, widely used and recommended by different authors and institutions.

In Part II (Vanhie et al., 2016 Part II), we have developed deliberately an exhaustive list of recommendations to avoid bias as much as possible. It is obvious that it is practically impossible to use all variables together in one study/register/database, and that investigators may be selective depending on their hypothesis and objectives. Nevertheless, in view of the recommendations listed in Part II (Vanhie et al., 2016 Part II), each investigator will be challenged to clearly document why certain CORDES outcome variables were included or omitted in their study. As such, the recommendations from Part II (Vanhie et al., 2016 Part II) will stimulate a more rigorous development of study protocols and better reporting of the results. To this end, our proposal will support the planning, execution and interpretation of high quality surgical trials that are urgently needed to better understand what constitutes optimal surgical treatment for women with DE, and that represent the only way to transform opinion into science.

Supplementary data

Supplementary data are available at <http://humrep.oxfordjournals.org/>.

Authors' roles

The paper was primarily designed and written by the first author A.V. and by last author T.D. All other coauthors contributed significantly to the content of this paper, added new concepts, provided additional relevant papers, critically reviewed and improved draft versions of this paper.

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Table II Standardized reporting of surgical trials for DE.

Methods	Report methods according to international standards: <ul style="list-style-type: none"> • CONSORT • STROBE • PRISMA
Participants	Record WERF-EPHect EPQ for all patients Report detailed description of the population studied <ul style="list-style-type: none"> • Age, BMI and ethnicity • Medication and substance use • Medical history and treatment • Menstrual history • Previous use of hormonal treatment • Previous diagnosis of endometriosis • Previous therapeutic surgery • Obstetrical history • Family history of endometriosis Report detailed description of pre-operative work-up <ul style="list-style-type: none"> • Details on imaging techniques used • Detailed description of results: pre-operative endometriosis mapping
Interventions	Report details on indications for surgery <ul style="list-style-type: none"> • Pain symptoms without infertility • Pain symptoms with infertility • Infertility without pain symptoms • No infertility or pain symptoms • Asymptomatic hydro-ureteronephrosis Report details on decisions on type/technique of surgery <ul style="list-style-type: none"> • Pre or intra-operative decision • Decision criteria/treatment algorithm Report interventions using the DESS: <ul style="list-style-type: none"> • Description endometriosis at start of surgery • Staging of endometriosis: ASRM + EFI (± ENZIAN) • Standardized description of all surgical procedures • Description of abdomen at end of surgery Report detailed histological results <ul style="list-style-type: none"> • Histologic confirmation of endometriosis + histologic type/pattern • Largest diameter of each lesion • Depth of invasion (in bowel, bladder, ureter, ...) for each lesion • Bowel specimens: <ul style="list-style-type: none"> • Presence of lymphatic dissemination • Median length of the resected bowel segments (in cm) • Number + location of positive section margins
Results	Report details on all primary outcomes Pain <ul style="list-style-type: none"> • Daily ratings with 11-point NRS • Separate ratings for: dyspareunia, dysmenorrhea, chronic pelvic pain, dyschezia and mictalgia • Record and report concomitant use of other drugs/analgesics/therapies • Address cyclicity: menstrual diary QoL <ul style="list-style-type: none"> • EHP-30

*Continued***Table II** Continued

- Assessment at baseline (minimum 1) + follow up (minimum 1)
- Fertility
- Report cumulative pregnancy rate
 - Report details on mode of conception
 - Report details on post-operative hormonal treatment (secondary prevention)
- Recurrence
- Report cumulative suspected and proven recurrence rate
- Complications
- Report all complications + management + outcome in absolute numbers
 - Classify complications according to Clavien-Dindo
 - Report comprehensive complication index (CCI)
- Report details on secondary outcomes
- Sexual function
- Define method use for assessment of sexual (dys)function
 - Assessment at baseline (minimum 1) + follow up (minimum 1)
 - Suggested PRO's:
 - FSFI = Female sexual function index
 - MFSQ = McCoy Female Sexuality Questionnaire
 - GSSI = Global Sexual Satisfaction Index
- Urinary function
- Define the method used for assessment of urinary (dys)function
 - Recommended use of PRO combined with urodynamics
 - Assessment at baseline (minimum 1) + follow up (minimum 1)
 - Suggested PRO: BFLUTS (=ICIQ-FLUTS)
- Bowel function
- Define the method used for assessment of bowel (dys)function
 - Assessment at baseline (minimum 1) + follow up (minimum 1)
 - Suggested PRO's:
 - General GI-symptoms: GIQLI
 - Constipation: KESS
 - Incontinence: FIQLI
 - Classification of feces: Bristol Stool Chart
- Optional: report details on tertiary outcomes
- Cost-effectiveness
- Recovery: QoR-40 or CARE
- Patient centeredness: ENDOCARE-questionnaire

WERF-EPHect EPQ, World Endometriosis Research Foundation Phenome and Biobanking Harmonisation Project; EPQ, Endometriosis Patient Questionnaire; NRS, numerical rating scale; QoL, quality of life; PRO, patient reported outcome; BFLUTS, Bristol Female Lower Urinary Tract Scale; ICIQ, International Consultation on Incontinence Modular Questionnaire; FLUTS, Female Lower Urinary Tract Symptoms; GIQLI, Gastrointestinal Quality of life Index; KESS, Knowles-Eccersley-Scott Symptom questionnaire; FIQLI, Fecal Incontinence Quality of Life scale.

Conflict of interest

M.A. reports personal fees and non-financial support from Bayer Pharma outside the submitted work; H.T. reports a grant from Pfizer and personal fees for being on the advisory board of Perrigo, Abbvie, Allergan and SPD.

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